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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	George Tachas et al.
APPLICATION NO.:	10/789,526
FILING DATE:	February 26, 2004
TITLE:	Modulation of Growth Hormone Receptor Expression and Insulin-Like Growth Factor Expression
EXAMINER:	Not yet known
GROUP ART UNIT:	1651
ATTY. DKT. NO.:	23546-08072 (BIOL00002US)

CERTIFICATE OF MAILING

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Dated: October 19, 2004 By: Susan T. Hubl
Susan T. Hubl, Reg. No.: 47,668

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INFORMATION DISCLOSURE STATEMENT
Under 37 CFR §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 CFR §§ 1.56 and 1.97-98, enclosed herewith is modified form PTO/SB/08A listing references for consideration by the Examiner.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:

- ☒ within three months of the filing date of the application, or date of entry into the national stage of an international application, or before the mailing date of a first office action on the merits, whichever event last occurred;
- ☐ before the mailing of a first official action after the filing of a request for continued examination (RCE) under 37 CFR § 1.114;
- ☐ after three months of the filing date of this national application or the date of entry of the national stage in an international application, or after the mailing

date of the first official action on the merits, whichever event last occurred, but before the mailing date of the first to occur of either: (1) a final action under 37 CFR §1.113; or (2) an action that otherwise closes prosecution in the application, and:

- ☐ attached hereto is the fee set forth under 37 CFR §1.17(p) for submission of this Information Disclosure Statement under 37 CFR.§ 1.97(c); OR
- ☐ Applicant certifies pursuant to 37 CFR § 1.97(e) that:
  - ☐ each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement; OR
  - ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 CFR § 1.56(c) more than three months prior to the filing of this Statement;

☐ on or before the payment of the issue fee but after the mailing date of the first to occur of either: (1) a final action under 37 CFR § 1.113; (2) a notice of allowance under 37 CFR § 1.311; or (3) an action that otherwise closes prosecution in the application, and:

- ☐ Applicant certifies pursuant to 37 CFR. § 1.97(e) that:
  - ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement;
  - ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated

under 37 CFR § 1.56(c) more than three months prior to the filing of this Statement; AND

☐ attached hereto is the fee set forth under 37 CFR §1.17(p) for submission of this Information Disclosure Statement under 37 CFR.§ 1.97(c); OR

☐ after the payment of the issue fee. Applicant requests that the information contained in this Information Disclosure Statement be placed in the file according to 37 CFR § 1.97(i), although the information may not be considered by the USPTO.

☒ Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose.

☐ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. _____ , filed on _____ , and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 CFR § 1.98(d).

☐ This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 CFR 1.98(a)(2)(i), copies of each U.S. Patent and each U.S. Patent Application Publication are not required to be submitted. Copies of any foreign patent documents and non-patent literature cited herein are enclosed.

☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 CFR § 1.56(c) more than thirty days prior to the filing of this Information Disclosure Statement. 37 CFR § 1.704(d).

☒ Applicant submits that no fee is required for the consideration of this Information Disclosure Statement.

Consideration of the listed references and favorable action are solicited.

Respectfully submitted,
GEORGE TACHAS ET AL.

Dated: October 19, 2004

By: _____

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 4

Complete if Known	
Application No.	10/789,526
Filing Date	February 26, 2004
First Named Inventor	George Tachas
Art Unit	1651
Examiner Name	Not yet known
Attorney Docket Number	23546-08072 (BIOL0002US)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document No. Number – Kind Code[2] (if known)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] – Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

OTHER REFERENCES – NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[6]
	C1	CHEN, N.-Y. et al., *A Growth Hormone Antagonist Protects Mice Against Streptozotocin Induced Glomerulosclerosis Even in the Presence of Elevated Levels of Glucose and Glycated Hemoglobin*, Endocrinology, Volume 137, No. 11, August 5, 1996, pages 5163-5165.	
	C2	COSCHIGANO, K. et al., *Assessment of Growth Parameters and Life Span of GHR/BP Gene-Disrupted Mice, Endocrinology*, Volume 141, No. 7, February 14, 2000, pages 2608-2613	

Examiner Signature		Date Considered	

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Sheet	2	of	4

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	C3	FLYVBJERG, A. et al., *Inhibitory Effect of a Growth Hormone Receptor Antagonist (G120K-PEG) on Renal Enlargement, Glomerular Hypertrophy, and Urinary Albumin Excretion in Experimental Diabetes in Mice*, Diabetes, Volume 48, 1999, pages 377-382	
	C4	FRIEND, K et al., *The Growth Hormone Receptor Antagonist Pegvisomant Exhibits Antitumor Activity in Multiple Preclinical Tumor Models*, Proceedings of the 200 NCI-EORTC-AACR Symposium, Volume 6 Supplement, November 2000	
	C5	FRIEND, K., *Cancer and the Potential Place for Growth Hormone Receptor Antagonist Therapy*, Growth Hormone & IGF Research 2001, Supplement A, 2001, pages S121-S123	
	C6	GRANT, M., *The Efficacy of Octreotide in the Therapy of Severe Nonproliferative and Early Proliferative Diabetic Retinopathy*, Diabetes Care, Volume 23, No. 4, April 2000, pages 504-509	
	C7	GRONBæK, H. et al., *Inhibitory Effects of Octreotide on Renal and Glomerular Growth in Early Experimental Diabetes in Mice*, Journal of Endocrinology, Volume 172, 2002, pages 637-643	
	C8	HIGGINS, R. et al., *Somatostatin Analogs Inhibit Neonatal Retinal Neovascularization*, Exp. Eye Res., Volume 74, 2002, pages 553-559	
	C9	LANDAU, D. et al., *A Novel Somatostatin Analogue Prevents Early Renal Complications in the Nonobese Diabetic Mouse, Kidney International*, Volume 60, 2001, pages 505-512	
	C10	LeROITH, D. et al., *Molecular and Cellular Aspects of the Insulin-Like Growth Factor I Receptor*, Endocrine Reviews, Volume 16, No. 2, 1995, pages 143-163	

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Attorney Docket Number	23546-08072

Sheet 3 of 4

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	C11	PARAN, D. et al., *A Pilot Study of a Long Acting Somatostatin Analogue for the Treatment of Refractory Rheumatoid Arthritis*, Ann. Rheum Dis., Volume 60, 2001, pages 888-891	
	C12	PARAN D. et al., *Probable Adverse Effects of Long Term Use of Somatostatin Analogues in Patients with RA*, Ann Rheum Dis., Volume 61, 2001, page 1117	
	C13	PELLEGRINI, E. et al., *Central Administration of a Growth Hormone (GH) Receptor mRNA Antisense Increases GH Pulsatility and Decreases Hypothalamic Somatostatin Expression in Rats*, Journal of Neuroscience, Volume 16, No. 24, December 15, 1996, pages 8140-8148	
	C14	RUBIN, R. et al., *Biology of Disease – Insulin-Like Growth Factor-I Receptor: Its Role in Cell Proliferation, Apoptosis, and Tumorigenicity*, Laboratory Investigation, Volume 73, No. 3, 1995, pages 311-331	
	C15	SEGEV, Y. et al., *Growth Hormone Receptor Antagonism Prevents Early Renal Changes in Nonobese Diabetic Mice*, J. Am., Soc. Nephrol., Volume 10, 1999, pages 2374-2381	
	C16	SERRI, O. et. al., *Somatostatin Analogue, Octreotide, Reduces Increased Glomerular Filtration Rate and Kidney Size in Insulin-Dependent Diabetes*, JAMA, Volume 265, No. 7, February 20, 1991, pages 888-892	
	C17	SJÖGREN, K. et al., *Liver-Derived Insulin-Like Growth Factor I (IGF-I) is the Principal Source of IGF-I in Blood But is Not Required for Postnatal Body Growth in Mice*, Proc. Natl. Acad. Sci. USA, Volume 96, June 1999, pages 7088-7092	
	C18	SMITH, L. et al., *Essential Role of Growth Hormone in Ischemia-Induced Retinal Neovascularization*, Science, Volume 276, June 13, 1997, pages 1706-1709	

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	C19	TRAINER, P. et al., *Treatment of Acromegaly with the Growth Hormone-Receptor Antagonist Pegvisomant*, The New England Journal of Medicine, Volume 342, No. 16, April 20, 2000, pages 1171-1177	
	C20	TURNLEY, A. et al., *Suppressor of Cytokine Signaling 2 Regulates Neuronal Differentiation by Inhibiting Growth Hormone Signaling*, Nature Neuroscience, Volume 5, No. 11, November 2002, pages 1155-1162	
	C21	ULLRICH, A., et al., *Insulin-like Growth Factor I Receptor Primary Structure: Comparison with Insulin Receptor Suggests Structural Determinants that Define Functional Specificity*, EMBO J., Volume 5, July 18, 1986, pages 2503-2512	
	C22	VAN DER LELY, A., et al., *Long-Term Treatment of Acromegaly with Pegvisomant, A Growth Hormone Receptor Antagonist*, The Lancet, Volume 358, November 24, 2001, pages 1754-1759	
	C23	VAN NECK, J., et al., *Dose-Response Effects of a New Growth Hormone Receptor Antagonist (B2036-PEG) on Circulating, Hepatic and Renal Expression of the Growth Hormone/Insulin-Like Growth Factor System in Adult Mice*, Journal of Endocrinology, Volume 167, 2000, pages 295-303	

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TRANSMITTAL FORM

(to be used for all correspondence during pendency of filed application)

Application Number	10/789,526
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First Named Inventor	George Tachas
Group Art Unit Number	1651
Examiner Name	NOT YET KNOWN
Total Number of Pages in This Submission: 8*	Attorney Docket Number: 23546-08072 (BIOL00021US)

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SIGNATURE OF ATTORNEY OR AGENT

Signature:	Susan T Hubl		
Attorney/Reg. No.:	Susan T. Hubl/47,668	Dated:	October 19, 2004

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Signature:	Susan T Hubl		
Typed or Printed Name:	Susan T. Hubl	Dated:	October 19, 2004
Express Mail Mailing Number *(optional)*:			